DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 25, 2015

Prosidyan, Incorporated
% Ms. Janice M. Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K143533
Trade/Device Name: FIBERGRAFT™ BG Putty Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: February 10, 2015
Received: February 10, 2015

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K143533

Device Name

FIBERGRAFT™ BG Putty - Bone Graft Substitute

Indications for Use *(Describe)*

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Prosidyan, Inc.'s BG Putty – Bone Graft Substitute

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Prosidyan, Inc.
30 Technology Drive
Warren, NJ 07059
Phone: (610)-945-5640
Facsimile: (908) 396-1151
Contact Person: Charanpreet S. Bagga

Date Prepared: December 12, 2014

Name of Device and Name

FIBERGRAFT™ BG Putty Bone Graft Substitute

Common or Usual Name

Bone Void Filler

Classification Name/CFR Regulation/Product Code

Resorbable Calcium Salt Bone Void Filler, 21 CFR 888.3045, product code MQV

Predicate Devices

- Prosidyan, Inc.'s FIBERGRAFT™ BG Morsels Bone Graft Substitute (K141956, K132805).
- NovaBone Products, LLC's NovaBone Putty- Bioactive Synthetic Bone Graft (K060728, K080009, K101860, K110368, K112773).

Intended Use / Indications for Use

FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Device Description

The FIBERGRAFT™ BG Putty is a osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable binder to form a cohesive material.

Technological Characteristics

The technological characteristics of the FIBERGRAFT™ BG Putty are similar to the Prosidyan, Inc. FIBERGRAFT™ BG Morsels Bone Graft Substitute cleared per K141956, K132805 and to NovaBone Products, LLC's NovaBone Putty Bioactive Synthetic Bone Graft cleared per K060728, K080009, K101860, K110368, K112773. The device is designed as an osteoconductive space-filling device to be gently packed into defect sites and used as a non-structural scaffold for the body's natural healing and bone regeneration process. The device indications are the same as for the predicate.

FIBERGRAFT™BG Putty provides an osteoconductive, resorbable, biocompatible bone graft substitute made from 45S5 bioactive glass mixed with a polymer carrier. Bioactive glass is defined as a group of glasses which has a compositional range that allows the formation of hydroxyapatite (HA) as a surface layer when exposed to an aqueous phosphate-containing solution such as simulated body fluid. The HA layer that forms in an aqueous phosphate-containing solution plays a significant role in forming a strong bond with natural bone. The bioactive glass in the FIBERGRAFT™ BG Putty is the same as the bioactive glass used in the FIBERGRAFT™ BG Morsels and Novabone Putty products. In addition, both the BG Putty and the Novabone Putty are provided in putty form using a resorbable polymer carrier.

Performance Data

The performance of the FIBERGRAFT™ BG Putty has been established by undertaking physical and chemical property evaluation studies, functional performance animal studies and biocompatibility tests. The physical and chemical property studies confirmed the *in vitro* functionality and bioactivity of the BG Putty. The in vitro bioactivity test results have not been correlated to clinical performance. The biocompatibility of the FIBERGRAFT™ BG Putty is demonstrated by ISO 10993 testing and the long history of clinical use of the bioactive glass material for the same intended use. In addition, the BG Putty is composed of the same bioactive glass material with the same bioactive glass chemical composition and the same type and duration of patient contact as the predicates. Packaging evaluations, shelf life testing and real time aging testing were performed with passing results.

The functional performance of the FIBERGRAFT™ BG Putty was evaluated in critical size defects in an ovine model, consistent with FDA's recommendations for Class II synthetic bone graft substitutes. Animal testing demonstrated evidence of new bone formation in critical size defects, with substantially equivalent performance compared to the predicate device. A total of 58 tested samples were evaluated in the study from skeletally mature sheep, including radiographic, histological, histomorphometric, and biomechanical data. Testing of the BG Putty in the ovine model is representative of the indications for use and range of anatomical sites proposed for the subject device. In addition, the study was conducted for a duration of 24 weeks with interim evaluation points. The results of the study demonstrated that the BG Putty device performs as safely and as effectively as the predicate device, and any differences between the results of the device groups do not raise new types of safety or effectiveness concerns.

Therefore, performance testing demonstrated that the BG Putty device functions as intended and meets the requirements of class II bone void fillers as compared to the predicate devices.

Substantial Equivalence

FIBERGRAFT™ BG Putty is substantially equivalent to the FIBERGRAFT™ BG Morsels and the Novabone Putty Bioactive Synthetic Bone Graft predicate devices. FIBERGRAFT™ BG Putty has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. In addition, the FIBERGRAFT™BG Putty is composed of the same bioactive glass material with the same chemical composition and the same type and duration of patient contact as the Prosidyan FIBERGRAFT™ BG Morsels Bone Graft Substitute and NovaBone predicates. The minor technological differences between BG Putty and its predicate devices do not raise any new issues of safety or effectiveness. Performance data demonstrate that BG Putty is equivalent to the predicate devices.

Conclusion

FIBERGRAFT™ BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute composed of bioactive glass, mixed with a polymer carrier. The FIBERGRAFT™ BG Putty is substantially equivalent to its predicate devices for its intended use as a synthetic bone void filler. Performance testing, including in vivo data, demonstrated that the device functions as intended without raising new safety or effectiveness questions.